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DAIG
a St. Jude Medical Company

510(k) Summary
(21 CFR Part 807.92)

A. Submitter Information

Submitter's Name:	Daig Corporation, a St. Jude Medical Company
Address:	14901 DeVeau Place Minnetonka, Minnesota 55345-2126 U.S.A.
Telephone Number:	(612) 933-4700
Fax Number:	(612) 930-9481
Contact Person:	Paul Cornelison, Manager of Regulatory Affairs
Date Submission Prepared:	December 30, 1999

B. Device Information

Trade Name:	Alliance™ Catheter Delivery System
Common or Usual Name:	Percutaneous Catheter Introducer
Classification Name:	Percutaneous Catheter Introducer (per 21 CFR Part 870.1200)
Device Classification:	Class II (per 21 CFR Part 870.1200) Panel – Cardiovascular
Predicate Devices:	Daig Corporation – Percutaneous Catheter Introducer with Peel-Away Sheath, 510(k) number K894431 Cardima, Inc. - Vueport™ Coronary Sinus Balloon Occlusion Guiding Catheter, 5109k) number K973298
Subject Device Description:	The Alliance™ Catheter Delivery System is a sterile, non-pyrogenic, single use only percutaneous catheter introducer with peel-away sheath and balloon.
Intended Use:	The Alliance™ Catheter Delivery System is designed to access the coronary sinus and perform occlusive venograms.

The Alliance may serve as a conduit for the delivery and support of other devices.

C. Comparison of Required Technological Characteristics

The technological characteristics of the Alliance™ Catheter Delivery System Introducer are similar to the following predicate devices: 1) Percutaneous Catheter Introducer with Peel-Away Sheath (K894431), manufactured by Daig Corporation and cleared by the FDA on September 06, 1989; and 2) Vueport™ Coronary Sinus Occlusion Balloon Guiding Catheter (K973298), manufactured by Cardima Inc. and cleared by the FDA on June 26, 1998.

D. Support of the Substantial Equivalence

Daig Corporation considers the Alliance™ Catheter Delivery System Introducer to be substantially equivalent to the following predicate devices:

- Percutaneous Catheter Introducer with Peel-Away Sheath manufactured by Daig Corporation, received marketing clearance on September 06, 1989 (K894431).
- Vueport™ Coronary Sinus Balloon Occlusion Guiding Catheter manufactured by Cardima Inc., received marketing clearance on June 26, 1998 (K973298).

Establishment of equivalence is based on similarities of intended use, design, and physical characteristics. Bench testing and biocompatibility studies were performed and the test results supported the substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2000

Mr. Paul Cornelison
Manager of Regulatory Affairs
St. Jude Medical
Daig Division
14901 DeVeau Place
Minnetonka, MN 55345

Re: K000004
Trade Name: Alliance™ Catheter Delivery System
Regulatory Class: II (two)
Product Code: DYB
Dated: August 30, 2000
Received: August 31, 2000

Dear Mr. Cornelison:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices:

General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000004

Device Name: Alliance™ Catheter Delivery System

Indications For Use:

The Alliance™ Catheter Delivery System is intended to access the coronary sinus and perform occlusive venograms and to serve as a conduit for the delivery and support of other devices.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K000004

(Optional Format 3-10-98)